Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Registration Decision RD2010-11

Garlic Powder

(publié aussi en français)

14 October 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100561

ISBN: 978-1-100-16827-2 (978-1-100-16828-9)
Catalogue number: H113-25/2010-11E (H113-25/2010-11E-PDF)

© **Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2010**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Registration Decision for Garlic Powder

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Garlic Powder Technical and Influence, containing the technical grade active ingredient garlic powder, to suppress powdery mildew on greenhouse cucumbers and tomatoes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-11, *Garlic Powder*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for garlic powder and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRDD2010-11. This decision is consistent with the proposed registration decision stated in PRD2010-11.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-11, *Garlic Powder* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*" ...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information, please refer to the following:

- Protecting Your Health and Environment
- Pesticide Registration Process
- Pesticide Risk Reduction Program

What Is Garlic Powder?

Garlic powder is the active ingredient in the end-product Influence. This wettable powder formulation is being registered in Canada for suppression of powdery mildew on greenhouse cucumbers and tomatoes.

Health Considerations

Can Approved Use of Garlic Powder Affect Human Health?

Garlic powder is unlikely to affect human health when used according to label directions.

Exposure to garlic powder may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, garlic powder, is of low acute toxicity by the oral and dermal routes and is slightly irritating to eyes and skin. Due to the irritative nature of garlic, inhalation exposure may cause throat irritation. There is potential for skin sensitization to occur when skin is repeatedly exposed to the garlic powder. Therefore, cautionary statements alerting users to this sensitization concern are required on product labels.

Inhalation and dermal exposures are likely for occupational workers and commercial applicators. Anyone entering the sprayed areas in the greenhouse before the spray is dried may be exposed dermally. Therefore, personal protective equipment and a restricted entry statement are required on the end-use product label to mitigate such exposure concerns.

Requests to waive short-term dermal toxicity, prenatal development toxicity and genotoxicity studies were accepted by the Pest management Regulatory Agency. Waivers were based on the anticipated low dermal absorption and on the strength of evidence that there is little indication of short or long term toxic effects resulting from garlic's long history of consumption as a food and in natural health products.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Garlic is used for culinary purposes world-wide and is also consumed for its medicinal values. Garlic powder is rapidly degraded in the environment, so exposure from residues in water and from treated food commodities is likely to be minimal. There is reasonable certainty that no harmful effects will occur from dietary exposure to garlic powder from the use of Influence.

Occupational Risks From Handling Influence

Occupational risks are not of concern when Influence is used according to label directions, which include protective measures.

Occupational exposure to individuals mixing, loading, or applying Influence is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Garlic Powder is Introduced Into the Environment?

Garlic is a commodity that is grown and used around the world for both cooking and medicinal purposes. Garlic powder is very soluble in water. It is widely distributed and commercially available in the food industry for flavouring and seasoning. Garlic powder is expected to degrade rapidly in the environment.

The environmental exposure from the use of garlic powder is expected to be minimal for the proposed use in greenhouses. Garlic powder was not toxic to honey bees, on an acute contact basis. Thus, risk to terrestrial arthropods is expected to be negligible.

Value Considerations

What Is the Value of Influence ?

Powdery mildew of greenhouse tomato and cucumber is a serious disease that leads to reduction in crop quality loss. The registration of Influence will provide an additional mode of action to manage this disease.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Influence to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words "POTENTIAL SKIN SENSITIZER" and the statement "May cause skin sensitization" are required on the principal and the secondary display panels, respectively, of both the technical and end-use product labels.

Mixer/Loader/Applicator and related workers are required to wear a long-sleeved shirt, long pants, water-proof gloves, shoes plus socks, and eye goggles when handling, mixing/loading or applying the product, and during all clean-up/repair activities. In addition, mixers and loaders must wear a dust/mist filtering respirator (dust mask) meeting a standard of at least N-95, R-95, P-95 or HE and applicators using a power sprayer must wear a bayonet-style cartridge respirator (for particulates) equipped with at least an N-95, R-95, P-95 or HE filter.

Both the technical product and the end use product labels have the statements, "CAUTION EYE IRRITANT" and "CAUTION SKIN IRRITANT" on the principal display panels, and the labels state that the handling of garlic powder and the end-use product be done in a well-ventilated room and caution handlers to avoid contact with eyes, skin and clothing.

Besides the statements "Avoid breathing dust." and "Avoid breathing dust and spray mists." on the technical product and the end use product labels, respectively, both the labels should include the statement, "May cause respiratory irritation." in the precaution sections.

To avoid bystander exposure, the Influence label states that unprotected persons should be kept out of the treated areas for the duration of the treatment period.

To prevent post-application exposure, the Influence label should have the restricted-entry statement, "Do not re-enter or allow re-entry into treated areas until the spray is dried."

To prevent microbial contamination of crops from spray solution, the Influence label should include the statement "Use freshly prepared spray solution each time" under directions for use.

Environment

Risk to non-target organisms is negligible. Environmental exposure will be mitigated by appropriate label precautions.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please visit Request a Reconsideration of Decision or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Reference Number: 1691824
Reference: 2008, Manufacturing process, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI

PMRA Reference Number: 1691827
Reference: 2008, Chemical and physical properties, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI

PMRA Reference Number: 1775019
Reference: 2009, Manufacturing methods, DACO: 2.11 CBI

PMRA Reference Number: 1775020
Reference: 2009, Manufacturing methods, DACO: 2.11 CBI

PMRA Reference Number: 1777453
Reference: Correspondence CBI

PMRA Reference Number: 1691849
Reference: 2008, Manufacturing process, DACO: 3.2.1,3.2.2,3.2.3 CBI

PMRA Reference Number: 1691850
Reference: 2008, Specifications + MSDS + form 6003, DACO: 3.3.1,3.3.2 CBI

PMRA Reference Number: 1691852
Reference: 2008, Chemical and physical properties, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI

PMRA Reference Number: 1691853
Reference: 2008, Storage stability, DACO: 3.5.10 CBI

PMRA Reference Number: 1775028
Reference: 2009, Container material and description, DACO: 3.5.5 CBI

2.0 Human and Animal Health

PMRA Reference Number: 1665152
Reference: 2008, Acute oral, INFP2-19, MRID: n/a, DACO: 4.2.1

PMRA Reference Number: 1665156
Reference: 2008, Acute dermal, INFP2-20, MRID: n/a, DACO: 4.2.2

PMRA Reference Number: 1665160
Reference: 2008, Primary eye irritation, INFP2-22, MRID: n/a, DACO: 4.2.4

PMRA Reference Number: 1665162
Reference: 2008, Primary dermal irritation, INFP2-23, MRID: n/a, DACO: 4.2.5

PMRA Reference Number: 1665164
Reference: 2008, Dermal sensitization, INFP2-24, MRID: n/a, DACO: 4.2.6

PMRA Reference Number: 1665134
Reference: 2008, MSDS Influence, INFP2-04, MRID: n/a, DACO: 0.9

PMRA Reference Number: 1665135
Reference: 2008, MSDS formulants, INFP2-05, MRID: n/a, DACO: 0.9.1

PMRA Reference Number: 1665180
Reference: 2008, Protocol, INFP2-33, MRID: n/a, DACO: 0.8

PMRA Reference Number: 1665136
Reference: 2008, Draft label, INFP2-06, MRID: n/a, DACO: 1.1.1

PMRA Reference Number: 1407490
Reference: 2007, Toxicology Studies (articles), GARLIPRO-09, MRID: S/O, DACO: 4.1 - 4.8

PMRA Reference Number: 1691856
Reference: Summary, Use Description. AEF Global, Inc. DACO 5.2

3.0 Environment

PMRA Reference Number: 1407494
Reference: 2007, Environmental Toxicology, DACO: 9.1,9.2.1,9.2.3.1,9.3.1,9.5.1,9.5.2.1,9.5.2.2, 9.6.1,9.6.2.4,9.6.2.5,9.6.3.1,9.6.3.2,9.8.1,9.8.2,9.8.4,9.8.5,9.9

PMRA Reference Number: 1603999
Reference: 2008, Acute Contact Toxicity Test with the Honey Bee (*Apis mellifera*), DACO: 9.2.4.1

PMRA Reference Number: 1604000
Reference: 2008, Dehydrated Garlic Powder - Acute Contact Toxicity Test with the Honey Bee, DACO: 9.2.4.1

PMRA Reference Number: 1691836
Reference: 2008, Summary environmental toxicology, DACO: 9.1

4.0 Value

PMRA Reference Number: 1691865
Reference: 2008, Value summary, INF-18, MRID: na, DACO: 10.1

PMRA Reference Number: 1691866
Reference: 2008, Mode of action, INF-19, MRID: na, DACO: 10.2.1

PMRA Reference Number: 1691867
Reference: 2008, Desciption of pest problem, INF-20, MRID: na, DACO: 10.2.2

PMRA Reference Number: 1691873
Reference: 2008, Rapport de recherche TOM/UL/01 (efficacy tomato), INF-26, MRID: na, DACO: 10.2.3.3

PMRA Reference Number: 1691874
Reference: 2008, Rapport de recherche 2008-AB-16 (efficacy tomato), INF-27, MRID: na, DACO: 10.2.3.3

PMRA Reference Number: 1691875
Reference: 2008, Rapport de recherche 2008-AB-23 (efficacy tomato), INF-28, MRID: na, DACO: 10.2.3.3

PMRA Reference Number: 1691876
Reference: 2008, Rapport de recherche CON/UL/02 (efficacy cucumber), INF-29, MRID: na, DACO: 10.2.3.3

PMRA Reference Number: 1691877
Reference: 2008, Rapport de recherche 2008-AB-15 (efficacy cucumber), INF-30, MRID: na, DACO: 10.2.3.3

PMRA Reference Number: 1691878
Reference: 2008, Rapport de recherche : 2008-AB-22 (efficacy cucumber), INF-31, MRID: na, DACO: 10.2.3.3

PMRA Reference Number: 1691879
Reference: 2008, Rapport de recherche CON/UL/01 (efficacy cucumber), INF-32, MRID: na, DACO: 10.2.3.3
PMRA Reference Number: 1691880
Reference: 2008, INFLUENCE formulations, INF-33, MRID: na, DACO: 10.2.3.3

PMRA Reference Number: 1691882
Reference: 2008, Non safety adverse effects, INF-35, MRID: na, DACO: 10.3.1

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

PMRA Reference Number: 1431705
Reference: K. K. Soudamini et. al., Mutagenicity and anti-mutagenicity of selected spices. Indian J. Physiol. Pharmacol. 1995, 39(4), 347-53.

PMRA Reference Number: 1431706
Reference: T.W. McGovern and S. LaWarre, Botanical Briefs: Garlic-Allium sativum. CUTIS, Vol. 67, March 2001. p.193.

PMRA Reference Number: 1751838
Reference: D. Judith et. al., Garlic: A review of its relationship to malignant disease. Preventative Medicine 1990, 19, 346-361.

PMRA Reference Number: 1751849
Reference: M. Seuri et. al., Three cases of occupational asthma and rhinitis caused by garlic. Clinical and Experimental Allergy 1993, 23, 1011-1014.

PMRA Reference Number: 1751921
Reference: Y. Shukla et. al., Cancer chemoprevention with garlic and its constituents. Cancer Letters 2006, 247, 161-181.

PMRA Reference Number: 1565056
Reference: Couturier P., Bousquet J., Occupational allergy secondary to inhalation to garlic dust (letter). J Allergy Clin Immunol 1982, 70, 145.

PMRA Reference Number: 1565074
Reference: Falleroni A. E., Zeiss C. R., Levitz D., Occupational asthma secondary to inhalation of garlic dust. J Allergy Clin Immunol 1981, 68, 156-160.